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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/314,159	05/19/99	MOSER	T 1579-367

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EXAMINER

HUNT, J

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED:

12/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/314,159

Applicant(s)
Moser et al.

Examiner
Jennifer Nichols, Nee Hunt

Group Art Unit
1642



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) 8, 9, 11, 12, and 15-24 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7, 10, 13, and 14 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I (claims 1-7, 10, 13, and 14), and species (b), without traverse in Paper No. 5 is acknowledged. The subject matter appears to be free of the prior art, and therefor the search was extended to include all species.

Claims 1-24 are pending in the application. Claims 8-9, 11-12, and 15-24 are withdrawn from consideration as being drawn to a non-elected invention. An action on the merits of claims 1-7, 10, and 13-14 follows.

Claim Rejections - 35 USC § 112

2. Claims 1-7, 10, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7, 10, 13, and 14 are unclear in the recitation of "angiostatin binding portion". It is not clear what would be considered an angiostatin binding portion and what would not. The level of binding necessary and the amount which would be considered a "portion" cannot be determined from the claims or disclosure.

Claims 1-7, 10, 13 and 14 are unclear because it cannot be determined if the test compound is present in step (I). Step (I) begins with the recitation of "contacting said test

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compound". Step (I) ends with the recitation "such that angiostatin can bind to said ATP synthase, or angiostatin binding portion thereof, in the absence of said test compound", but yet step (I) only recites a single method step, and therefor it is not clear how the test compound can be part of the instant method, yet absent from it concurrently. As it is currently recited, it is not clear if this requirement is describing the "conditions" of the reaction, or is a requirement of the method step itself.

Claims 4-7 are unclear in the recitation of "is associated with a lipid membrane". The metes and bounds of "is associated with" cannot be determined. It is not clear what would be considered "associated with" and what would not.

Claims 10 and 13-14 are unclear in the recitation of "modulate a bioactivity". The metes and bounds of "modulate" cannot be determined. It is not clear what would be encompassed by "modulate" and what would not. Further, "bioactivity" is not clear. It is not clear what would be considered a bioactivity and what would not.

3. Claims 1-7, 10, and 13-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening which uses angiostatin, a test compound, and ATP synthase, does not reasonably provide enablement for the same screening method using angiostatin, a test compound, and any and all angiostatin binding portions of ATP synthase. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining scope and enablement are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented in the specification, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art, 7) the predictability of the unpredictability of the art, and 8) the breadth of the claims (see *Ex parte Forman*, 230 USPQ 546, BPAI, 1986).

There is no guidance or objective evidence that binding portions of ATP synthase would function in assays as the full polypeptide does. The instant specification sets forth guidance and examples of assays which test angiostatin binding to full length ATP synthase for the purpose of measuring a test compound's effect on angiostatin binding to ATP synthase. There is no evidence or guidance that would lead one of skill in the art to conclude that the binding fragment would function as the full length polypeptide does, and thus be reflective of cellular activity in vivo. It is well established in the art that protein structure and function are unpredictable, with just a minor change often having a major impact on the structure and function of that protein. Thus although the "binding portion" of ATP synthase *might* still bind angiostatin, there is no evidence or guidance that would indicate that it was reflective of the full length polypeptide for evaluating compounds which would inhibit such binding.

Therefor one of skill in the art would not be enabled to practice the full scope of the invention as claimed.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Nichols, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.


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Jennifer Nichols, Nee Hunt

December 17, 2000


JENNIFER NICHOLS
PATENT EXAMINER
TECHNOLOGY CENTER 1600